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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,531	02/25/2005	Mitsuru Kuribayashi	MUR-046-USA-P	7067

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EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,531	KURIBAYASHI ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7,9 and 12-15* is/are pending in the application.

4a) Of the above claim(s) *15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 5, 7, 9 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/15/2010 has been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1, 4-5, 7, 9, and 12-13 under 35 U.S.C. 103(a) as being unpatentable over EP 1133985 (EP '985) in view of Nowicki (Medicine & Science in Sports & Exercise, 2002) is maintained.

Applicant argues EP '985 does not teach a water-soluble steroid hormone. Further, EP '985 does not teach a neutral acid but instead teaches polyacrylic acid. In the present invention, in order to obtain a gel the same as EP '985, an acid polymer would have to be present in very high concentration, and if an acidic polymer is present in such a very high concentration, the blood level of drug would not be obtainable. Further, if the basic drug of EP '985 is substituted with a nonionic water soluble steroid hormone, gelatinization of the composition would not be possible. Nowicki does not make up the deficiencies of EP '985. Further, claim 1 has been amended to recite "consisting essentially of".

Applicant's arguments have been fully considered but are not found persuasive.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA

1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). See MPEP 2111.03

The adhesive gel of EP '985 may comprise an acidic polymer such as polyacrylic acid, which corresponds to Applicant's ionic synthetic polymer(s) (A). Applicant argues that the claimed invention requires a neutral acid polymer because otherwise gelatinization would not be possible. This limitation, however, is not in the claims. The claims require "0.1 to 3.0% by wt. of ionic synthetic polymer(s) (A)". Polyacrylic acid meets this limitation. The Examiner notes that polyacrylic acid is disclosed in claim 5 as an acid which meets this limitation, i.e. it meets the "ionic synthetic polymer(s)" of claim 1. Further, nonionic synthetic polymers may be incorporated into the gel of EP '985, including polyvinylpyrrolidone and polyvinyl alcohol as binders. The incorporation of polyvinylpyrrolidone and/or polyvinyl alcohol corresponds to Applicant's nonionic synthetic polymer(s) (B). The adhesive gel may comprise gelatin, which correspond to

Applicant's naturally-occuring polymer(s) (C). The adhesive gel may comprise a polyhydric alcohol such as polyethylene glycol, which corresponds to Applicant's polyhydric alcohol(s). Further in contrast to Applicant's arguments, the claims do not require a "nonionic water-soluble steroid hormone", (page 5, last paragraph of reply) but a water-soluble steroid hormone which forms anion in the adhesive gel composition. As stated previously in the record, it would have been obvious to incorporate dexamethasone sodium phosphate (a water-soluble steroid hormone which forms anions in the adhesive gel), as Nowicki teaches administration of corticosteroids, such as dexamethasone sodium phosphate, for the treatment of inflammation. It would have been obvious to incorporate dexamethasone sodium phosphate (a water-soluble steroid hormone) as the anti-inflammatory agent of EP '985 to treat inflammation.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-5, 7, 9, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1133985 (EP '985; document already in record) in view of Nowicki (Medicine & Science in Sports & Exercise, 2002; document already in record) in further view of US 5682726 ('726; document already in record).

EP '985 discloses an adhesive gel for iontophoretic formulations (see abstract). The adhesive gel may comprise an acidic polymer such as polyacrylic acid (an ionic synthetic polymer), a nonionic synthetic polymer, gelatin (a naturally-occurring polymer), a polyhydric alcohol such as glycerin, a polyfunctional epoxy compound (a crosslinking agent), and a drug (paragraphs 19-28). The adhesive gel of EP '985 meets all the structural limitations of the claimed adhesive gel and it would therefore be fully capable of being delivered from the cathode side. Except for the instantly disclosed weight percents and the choice of water-soluble steroid hormone(s) as the drug, this satisfies

instant claims 1, 4-5, and 7, and 9. Several nonionic synthetic polymers may be incorporated into the gel, including polyvinylpyrrolidone and polyvinyl alcohol as binders (paragraph 24), and polyethylene glycol as one of the one or more polyhydric alcohols (see paragraph 26). Regarding instant claim 4, polyacrylic acid has anionic functional groups in the monomer unit ($CH_2CH_2COO^-$) which satisfies this claim. The gel can be adjusted to a pH of between 3 to 7 (paragraph 22), which satisfies instant claim 13. EP '985 teaches adding anti-inflammatory agents as the drug (paragraphs 29 and 35).

EP '985 fails to disclose water-soluble steroid hormones. EP '985 further fails to teach the weight percents of components as required by instant claim 1. EP '985 further fails to disclose an adhesive gel wherein oxygen dissolved in the gel is positively removed by placement with nitrogen and/or vacuum kneading at the time the ingredients are added and kneaded.

Nowicki teaches administration of corticosteroids, such as dexamethasone sodium phosphate, for the treatment of inflammation (page 1294). Administration of these compounds by iontophoresis is noninvasive, atraumatic, and painless, which offers advantages over traditional injection of the same agents (pages 1294 and 1301; Conclusions).

'726 teaches that oxygen levels in iontophoresis compositions may be reduced by a number of techniques, including replacing oxygen with an inert gas such as nitrogen and/or incorporating an oxygen scavenger such as sodium metalsulphite (col 3, lines 19-44; col 5, lines 1-11). The purpose of removing oxygen is to increase the

stability and shelf life of the drug (abstract). This technique is suited for iontophoretic compositions (col 4, lines 19-22).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to incorporate dexamethasone sodium phosphate (a water-soluble steroid hormone) as the anti-inflammatory agent of EP '985 to treat inflammation. The art recognizes that dexamethasone sodium phosphate is preferably administered by iontophoresis owing to the noninvasive, atraumatic, and painless nature of iontophoretic delivery. The adhesive gel of EP '985 offers a high efficacy means for delivering the anti-inflammatory to the patient via iontophoresis. It would therefore have been obvious to deliver dexamethasone sodium phosphate using the adhesive gel of EP '985.

It would have been further obvious to optimize the amount of the ionic synthetic polymer (A), nonionic synthetic polymer (B), and naturally-occurring polymer (C) in the gel to achieve a pH of between 3 to 7 and improved efficacy of the drug. In this way, one would find the weight percents disclosed in instant claim 1 through routine experimentation. EP '985 provides sufficient guidance to this end. EP '985 teaches that the polyacrylic acid (A) is added to adjust the pH and may be present from 1 to 20% by weight (paragraph 23). EP '985 further teaches that polyethylene glycol (B) may be present in 10 to 60% by weight (paragraph 26). EP '985 further teaches that the gelatin (C) (the naturally-occurring polymer) may be present from 0.1 to 15% by weight (paragraph 28). These ranges fully overlap with Applicant's ranges in instant claim 2. These ranges also fully satisfy the equations $(B + C)/A \geq 1.5$ and $A + B + C \geq 7\%$ in

instant claim 3. If the maximum of each of these ranges is taken, then (B + C)/A = (60 + 15)/(20) = 3.8 ≥ 1.5 and A + B + C = 20 + 60 + 15 = 95% ≥ 7%. "'[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" MPEP § 2144.05, II.

It would have been further obvious to remove oxygen from the adhesive gel of EP '985 by the technique taught by '726. The art recognizes that removing the oxygen will result in a product with a longer shelf life. The oxygen removal techniques taught by '726 are not identical to the removal technique of instant claim 14, the latter encompassing positively removing the oxygen by replacement with nitrogen and/or vacuum kneading at the time the ingredients are added and kneaded. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP § 2113. In the instant case, the same product will be made (i.e. an adhesive gel with decreased levels of oxygen) whether the oxygen is removed by the steps of '726 or the steps of instant claim 14. In other words, Applicant's adhesive gel which is deoxygenated by the method steps of instant claim 14 is indistinguishable from the adhesive gel of EP '985 which is deoxygenated according to the techniques of '726. For this reason, the product of

instant claim 14 is patentably indistinct from the product rendered obvious by EP '985 in view of Nowicki and '726.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PAUL DICKINSON/
Examiner, Art Unit 1618

February 25, 2011